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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,761	02/07/2002	Clark T. Hung	20076.73	7596

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EXAMINER

BEISNER, WILLIAM H

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/049,761

Applicant(s)

HUNG ET AL.

Examiner

William H. Beisner

Art Unit

1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/22/05 has been entered.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 43 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 43 and 44, "the fluid pressure" lacks antecedent basis. Note claim 29 is silent with respect to "fluid pressure".

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1744

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 13-19, 22-35, 58-60 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al.(WO 98/40111) as evidenced by Lee et al.(Journal of Orthopaedic Research).

With respect to claim 29, the reference of Lee et al.('111) discloses a method for producing functional cartilaginous tissue from a cell-seeded scaffold or a cell-seeded scaffold integrated with an osteoconductive and/or osteoinductive substrate, wherein the method includes inoculating chondrocytes into a scaffold or biocompatible substrate, placing the cell-seeded scaffold or substrate into a bioreactor, applying a strain-controlled deformational loading to the seeded scaffold or substrate via loading platens according to a load regime optimized for cartilaginous tissue growth; and culturing the scaffold or substrate for a time sufficient to produce functional cartilaginous tissue (See page 14, lines 9-27; Example 6 and Example 10). Note, the reference of Lee et al.(Journal of Orthopaedic Research) is cited as evidence that the bioreactor employed in Example 10 includes loading platens and control electronics for providing the strain-controlled deformational loading of the scaffolds or substrates (See Figure 1 and pages 182-183 of Lee et al.(Journal of Orthopaedic Research)). The use of multiple references in a 35 USC 102 rejection is proper when the extra reference provides evidence of what already exists in the primary reference (See M.P.E.P. 2131.01).

With respect to claims 1, 30 and 62, the bioreactor employed by Lee et al.('111) includes a growth chamber and means for applying strain-controlled deformational loading via loading platens (See Figure 1 and pages 182-183 of Lee et al.(Journal of Orthopaedic Research)).

Art Unit: 1744

With respect to claims 2-5 and 22-28, in the absence of further positively recited structure of the device, the system of the primary reference is considered to be capable of producing and/or operating of tissue as recited in these dependent claims.

With respect to claims 13-19, the system of the primary reference is structurally capable of providing the loading regimes of claims 13-19. /

With respect to claims 31-34, the reference of Lee et al.('111) discloses that the substrate material can be biodegradable, bioresorbable, biocompatible and/or non-resorbable (See page 8, lines 8-13).

With respect to claim 35, the implant material resulting from the treatment disclosed by the reference of Lee et al. ('111) is considered to produce an implant material with the claimed properties of claim 35.

With respect to claims 58-60, the bioreactor and/or platens are capable of producing tissue of a desired shape that can be implanted.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

Art Unit: 1744

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 45-51 and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al.(WO 98/40111) as evidenced by Lee et al.(Journal of Orthopaedic Research).

The reference of Lee et al.('111) as evidenced by the reference of Lee et al.(J. Orth. Res.) has been discussed above.

With respect to the strain loading of claims 45-51, the reference of Lee et al.('111) (See page 14, line 9, to page 15, line 20) discloses that the object of the treatment system is to expose the tissue constructs to loading that resembles the physiological conditions typically encountered by the tissue being replace and/or repaired.

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the typical conditions that the desired tissue would

Art Unit: 1744

be exposed to and operate the device to mimic those physiological conditions in terms of loading, frequency and length of time.

With respect to claims 54-57, while the reference of Lee et al.('111) discloses that the implant is used for repair of damaged connective tissue, the reference is silent with respect to the specifics of the implant (See page 16, lines 4-20). However, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the specific type of cartilage produced based merely on the intend use of the cartilage in terms of the location in the body it is intended to be implanted.

10. Claims 6-12, 20, 21, 36-44, 52, 53, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al.(WO 98/40111) as evidenced by Lee et al.(Journal of Orthopaedic Research) taken further in view of Nevo et al.(US 2002/0009805).

The reference of Lee et al.('111) as evidenced by the reference of Lee et al.(J. Orth. Res.) has been discussed above.

With respect to claims 6-12, 20, 21, 36-44, 52, 53, 62 and 63, while the reference of Lee et al. ('111) discloses that hydrostatic pressure is a known means for loading tissue implants prior to implantation (See page 14, lines 22-24), the instant claims require the combination of the strain and hydrostatic loading.

The reference of Nevo et al. discloses that it is known in the art to maintain tissue constructs under culture conditions that control the hydrostatic pressure that the tissue is exposed to (See paragraphs [0049] and [0059]).

Art Unit: 1744

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the system of the primary reference to include hydrostatic loading as suggested by Nevo et al. for the known and expected result of providing an additional means recognized in the art for ensuring that the cultured cells are exposed to conditions that mimic physiological conditions and for improving the contact of the culture medium within in pores of the porous scaffold material during the culture process. With respect to the specific loading conditions, it would have been obvious to one of ordinary skill in the art at the time the invention was made to determine the typical conditions that the desired tissue would be exposed to and operate the device to mimic those physiological conditions in terms of loading, frequency and length of time.

Response to Arguments

11. Applicant's arguments, see pages 16-21, filed 6/22/05, with respect to the rejection(s) of claim(s) claims 1-29, 31-44 and 59-61 under 35 USC 102 and 103 over Peterson alone or Fofonoff et al. in view of Peterson have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of the references of Lee et al.('111), Lee et al.(J. Orth. R.) and Nevo et al.


Conclusion

Art Unit: 1744

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-1142. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


William H. Beisner
Primary Examiner
Art Unit 1744

WHB